R striction Requirement

In Paper No. 11, the Examiner required restriction under 35 U.S.C. § 121 to one of four groups as follows:

I. Claims 27, 28, 32, 33, 38, 39, 43, 44, drawn to a polypeptide, obtained by the amplification of DNA sequence and expression in a host cell, classified in class 435, subclass 91.2.

II. Claims 29, 31, 40, 42, drawn to an antibody directed against the polypeptide, classified in class 530, subclass 389.1.

III. Claims 30, 41, drawn to a method of using the antibody for viral detection, classified in class 435, subclass 7.1.

IV. Claims 34-37, 45-48, drawn to a nucleotide, classified in class 536, subclass 23.72.

(Paper No. 11, p. 2)

Applicants provisionally elect to prosecute with traverse, Group I, claims 27, 28, 32, 33, 38, 39, 43, 44, drawn to a polypeptide fragment of a viral protein.

Section 803 of the M.P.E.P. states that "[i]f the search and examination of the entire application can be made without serious burden, the examiner must examine it on the merits . . . ." M.P.E.P. § 803 (emphasis added). Applicants respectfully point out that the Office has not demonstrated the serious burden of examining all of the pending claims together. Indeed, applicants note that similar claims directed to polypeptides, antibodies, and methods of using the antibody for diagnosing viral infection were examined together in related application S.N. 9/092,077 (now U.S. Patent No. 6,194,142). In addition, an exhaustive search of Group I (claims 27, 28, 32, 33, 38, 39, 43, and 44), drawn to a polypeptide fragment of a viral protein expressed by amplifying

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a DNA sequence with specific nucleic acids, would encompass any art disclosing the specific nucleic acids recited in claims 34-37 and 45-48 (Group IV).

The Examiner has further required an election of a single forward primer, a single reverse primer, and a single viral strain as follows:

Forward Primer:

(A) SEQ ID NO: 68;
(B) SEQ ID NO: 46;
(C) SEQ ID NO: 48;
(D) SEQ ID NO: 49;
(E) SEQ ID NO: 52;
(F) SEQ ID NO: 53;
(G) SEQ ID NO: 55; and
(H) SEQ ID NO: 56.

Reverse Primer:

(I) SEQ ID NO: 47;
(J) SEQ ID NO: 50;
(K) SEQ ID NO: 51;
(L) SEQ ID NO: 54; and
(M) SEQ ID NO: 57.

Viral Strain:

(N) SIV;
(O) HIV-1 Bru;
(P) HIV-1 Mal;
(Q) HIV-1 Eli; and
(R) HIV-2.

Applicants elect with traverse: 1) forward primer (C) SEQ ID NO: 48, 2) reverse primer (K) SEQ ID NO: 51, and 3) viral strain (O) HIV-1 Bru.

Regarding the forward and reverse primers, the Office asserts that the primers are unrelated and "represent structurally different polynucleotides." Applicants note that

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elected Group I is directed to polypeptides—not polynucleotides. The Office further asserts that "where structural identity is required, such as for hybridization or expression, the different sequences have different effects." As explained below, however, the different polynucleotide sequences recited in the claims actually share a common effect.

The claims of Group I are directed to polypeptide fragments encoded by a nucleotide sequence from an HIV-1, HIV-2, or SIV viral genome. The nucleotide sequence is amplified from the viral genome using a unique pair of primers, which contain sequences that are conserved between different HIV and SIV strains. The primers are insensitive to variations in the genomes of different HIV and SIV isolates and, therefore, can be used to amplify nucleotide sequences from different HIV-1, HIV-2, and SIV strains. Thus, the different sequences have the same effect, i.e., the different primers can be paired together and used to amplify nucleotide sequences from the different viral strains. Because the different primers contain sequences that are conserved among the different viral strains, they can be used to achieve this common effect.

Regarding the different viral strains, the Office asserts that "[i]nventions (N)-(R) are unrelated" and "represent structurally different polypeptides." Due to the conserved nature of the primer sequences, applicants note that at least the ends of any amplified sequence (as well as the region of any translated protein corresponding to the ends of amplified nucleotide sequence) would be conserved among the different viral strains. In

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addition, at a minimum, applicants respectfully assert that the HIV-1 strains (i.e., HIV-1 Bru, HIV-1 Mal, and HIV-1 Eli) should be examined together due to their structural similarity. As shown in Tables II-IV of the specification, amplifying these related strains with different combinations of primers yields nucleic acid molecules that have an identical or nearly identical length, suggesting that the amplified nucleic acids share homologous sequences.

Accordingly, applicants respectfully request that the Office withdraw the restriction of each of Groups I-III into a single combination of a forward primer, a reverse primer, and a viral strain.

CONCLUSION

In view of the foregoing remarks, applicants respectfully request the examination on the merits of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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